have solved the same problem as distinct considerations bearing on the obviousness inquiry. In contrast, the decision below erases any distinction. Pet. App. 23a-24a. The Court should not permit that result.

The requirement of nonobviousness traces back to this Court's decision in *Hotchkiss* v. *Greenwood*, 52 U.S. (11 How.) 248 (1851), but it was not codified until 1952. *See Graham*, 383 U.S. at 11-12, 15. In 1966, the Court concluded that the statutory provision "was intended merely as a codification of judicial precedents embracing the *Hotchkiss* condition." *Id.* at 17. The Court then described four "basic factual inquiries" that underlie analysis of nonobviousness:

(1) "the scope and content of the prior art";

(2) "differences between the prior art and the claims at issue";

(3) "the level of ordinary skill in the pertinent art"; and

(4) "[s]uch secondary considerations as *commercial success*, long felt but unsolved needs, *failure of others*, etc."

Id. at 17-18 (emphasis added).[3]

Before this case, the Federal Circuit followed *Graham*, treating commercial success and "failure of others" as separate secondary indicators of nonobviousness. *See, e.g.*, *Brown & Williamson Tobacco Corp.* v. *Philip Morris Inc.*, 229 F.3d 1120, 1129-1130 (Fed. Cir. 2000); *Ecolochem, Inc.* v. *Southern Cal. Edison Co.*, 227 F.3d 1361, 1376-1378, 1380 (Fed. Cir. 2000). In this case, however, the court took a sharp turn, holding that the "rationale" for considering

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[3] In the companion case of *United States* v. *Adams*, 383 U.S. 39, 51-52 (1966), the Court cited multiple "secondary considerations" supporting nonobviousness. In two later decisions, the Court has clarified that "secondary considerations" such as commercial success do not supplant the basic inquiry into whether there was an "invention." *Sakraida* v. *Ag Pro, Inc.*, 425 U.S. 273, 278-279, 282-283 (1976); *Anderson's-Black Rock, Inc.* v. *Pavement Salvage Co.*, 396 U.S. 57, 61 (1969).

commercial success "has no force" unless the success supports an inference of "failure of others." Pet. App. 23a-24a.

That holding conflicts with this Court's consistent recognition that commercial success *intrinsically* supports patentability. In *Smith* v. *Goodyear Dental Vulcanite Co.*, 93 U.S. 486, 495 (1876), the Court reasoned that success could help "justify the inference" that an innovation involved more than a mere design choice or "substitution of one material for another" and "was, in truth, invention." Later cases repeatedly relied on commercial success as evidence of patentability without requiring that it be evidence of "failure of others." *E.g.*, *Hobbs* v. *Beach*, 180 U.S. 383, 393 (1901); *Topliff* v. *Topliff*, 145 U.S. 156, 164 (1892); *Washburn & Moen Mfg. Co.* v. *Beat 'Em All Barbed-Wire Co.*, 143 U.S. 275, 284, 292 (1892); *Magowan* v. *New York Belting & Packing Co.*, 141 U.S. 332, 343 (1891); *Consolidated Safety-Valve Co.* v. *Crosby Steam Gage & Value Co.*, 113 U.S. 157, 179 (1885). To the contrary, the Court recognized that commercial success, "*of itself*, is persuasive evidence of ... invention." *Minerals Separation, Ltd.* v. *James M. Hyde*, 242 U.S. 261, 270 (1916) (emphasis added); *see also Keystone Mfg. Co.* v. *Adams*, 151 U.S. 139, 143-144 (1894) ("fact that a device has gone into general use, and has displaced other devices ...," "is always of importance, and is entitled to weight, when the question is whether the machine exhibits patentable invention"); *cf. Goodyear Tire & Rubber Co.* v. *Ray-O-Vac Co.*, 321 U.S. 275, 279 (1944). *Graham* acknowledged and preserved this line of precedent by listing "commercial success" as the first of the three "secondary considerations" that it expressly mentioned as part of the obviousness analysis. 383 U.S. at 17-18; *see also id.* at 35-36 (citing *Reiner* v. *I. Leon Co.*, 285 F.2d 501, 504 (2d Cir. 1960) (L. Hand, J.)).

Following *Graham*, courts of appeals repeatedly recognized the probative value of commercial success without tying it to "failure of others." *E.g.*, *Sarkisian* v. *Winn-Proof Corp.*, 697 F.2d 1313, 1320 (9th Cir. 1983); *Black & Decker Mfg. Co.* v. *Sears, Roebuck & Co.*, 679 F.2d 1101, 1104 (4th Cir. 1982); *Illinois Tool Works, Inc.* v. *Sweetheart Plastics,*

Inc., 436 F.2d 1180, 1187 (7th Cir. 1971). After the Federal Circuit was created in 1982, it too recognized commercial success as an independent factor supporting nonobviousness—even when there was "no evidence" of failure of others. *Brown & Williamson*, 229 F.3d at 1130-1131 ("district court erred by not considering the success" of a product, despite findings of "no evidence" of failure of others, "no long-felt but unmet need," and "no unexpected results"); *Ecolochem*, 227 F.3d at 1378, 1380 (affirming findings of "no long-felt but unsolved need" and "no failure by others," but holding that "district court clearly erred" in failing to credit evidence of "commercial success"); *see also* Rochelle Cooper Dreyfuss, *The Federal Circuit: A Case Study in Specialized Courts*, 64 N.Y.U. L. Rev. 1, 9 (1989) ("[T]he CAFC now requires evidence concerning the commercial success of patented invention, on the theory that the willingness of others to buy it demonstrates the extent to which it contributes to the field.").

That traditional approach makes perfect sense. It is not true that commercial success suggests nonobviousness only to the extent it provides "a basis for inferring that [other] attempts [to solve a problem] have been made and have failed." Pet. App. 23a (internal quotation marks omitted). For example, courts have recognized that third-party praise of an innovation can independently suggest that the invention involved was not obvious. *Ecolochem*, 227 F.3d at 1380; *see also Vulcan Eng'g Co.* v. *Fata Aluminum, Inc.*, 278 F.3d 1366, 1373 (Fed. Cir. 2002). Commercial success can be viewed as a particularly meaningful form of praise by the "interested public." *Arkie Lures, Inc.* v. *Gene Larew Tackle, Inc.*, 119 F.3d 953, 957-958 (Fed. Cir. 1997); *see also Illinois Tool Works*, 436 F.2d at 1187 ("We do not believe that the tribute of the trade and the marketplace can be ignored when it is so overwhelming in scope and magnitude."). This is especially true where the invention has a "specialized market" of "experts"—such as the physicians who prescribed weekly-dose Fosamax® in dramatically increased numbers. Spencer H. Boyer, *Commercial Success as Evidence of Patentability*, 37 Fordham L. Rev. 573, 594 (1969).

Commercial success also supports an inference of nonobviousness by providing objective, non-technical proof of significant, real-world differences between the claimed invention and prior products. *See Gillette Co.* v. *S.C. Johnson & Son, Inc.*, 919 F.2d 720, 725 (Fed. Cir. 1990). In the pharmaceutical arts, the discovery of unexpected properties is frequently the basis for awarding a patent for a specific compound, even where the larger chemical genus that includes the compound was disclosed by (or obvious in light of) the prior art. *See In re Papesch*, 315 F.2d 381, 386-391 (C.C.P.A. 1963) (discussing cases); *see also In re Soni*, 54 F.3d 746, 749-751 (Fed. Cir. 1995). The commercial success of a claimed compound can corroborate more technical evidence of such unexpected properties by showing that a knowledgeable and unbiased marketplace recognized the claimed invention as a substantial advance over what was available before. *See, e.g., Ortho-McNeil Pharm., Inc.* v. *Mylan Labs., Inc.*, 348 F. Supp. 2d 713, 755-757, 760-761 (N.D. W. Va. 2004); *cf. Sarkisian*, 697 F.2d at 1320-1321 (commercial success "support[ed court's] determination that [portable-stand] device produced results that were unusual or surprising").

Similarly, courts have recognized that commercial success is evidence "that the patent under attack served to satisfy a long felt want." *Lorenz* v. *F.W. Woolworth Co.*, 305 F.2d 102, 104-105 (2d Cir. 1962) (internal quotation marks omitted); *see also Greening Nursery Co.* v. *J&R Tool Mfg. Co.*, 376 F.2d 738, 742 (8th Cir. 1967). Long-felt need can, in turn, support nonobviousness even without an inference of "failure of others." Long-felt need can corroborate a claim that an invention solved a real-world problem and thus represented more than a design choice. Further, the long-established existence of this demand can show that even the holder of a patent in an underlying invention, such as Merck, had an incentive to develop a desired improvement substantially earlier. *Cf.* Richard L. Robbins, Note, *Subtests of "Nonobviousness": A Nontechnical Approach to Patent Validity*, 112 U. Pa. L. Rev. 1169, 1172 (1964) ("[e]xistence of [a] defect creates a demand for its correction, and it is reasonable to infer that the defect would not persist were the

solution 'obvious'"), *cited in Graham*, 383 U.S. at 36, *and in the opinion below*, Pet. App. 23a. The original patent holder's failure to do so, like "failure of others," supports a conclusion of nonobviousness.

In sum, the Federal Circuit's treatment of commercial success in this case defies this Court's decisions, other long-standing precedent, and the logic underlying both. As this Court has recognized, commercial success is a powerful *general* indicator that an inventor has contributed something new and patent-worthy to the art. The objective approval of the marketplace is strong evidence of genuine innovation. *Safety Car Heating & Lighting Co.* v. *General Elec. Co.*, 155 F.2d 937, 939 (2d Cir. 1946) (L. Hand, J.) ("the extent to which [an invention] superseded what had gone before" is "perhaps most important" among factors in "apprais[ing] the originality involved"). It should weigh heavily in favor of patentability regardless of whether there is additional evidence of a competitive market in the "race to invent."

II. Precluding Consideration Of Commercial Success Because Of Prior Exclusive Rights Improperly Truncates The Obviousness Inquiry And Reduces Incentives For Innovation

Even if commercial success were relevant only to support an inference of failure of others, the Federal Circuit would still have erred in reasoning that such failure cannot be inferred where the inventor of an improvement also had other rights under U.S. patent and drug laws that might have restricted third-party activity (Pet. App. 23a-24a).

The Federal Circuit's per se rule against such an inference is not grounded in evidence or in market reality. First, the inventors who develop an improvement may (as here) be employees of an entity that holds pre-existing rights, while the "others" who fail to develop the improvement may be other employees, affiliates, or licensees of the same entity. In this very case, when Merck in the mid-1990s sponsored research on the gastrointestinal side effects of alendronate, that research, if anything, taught away from the weekly dos-

ing schedule later developed by Merck inventors. Pet. App. 87a-88a.

Second, the existence of exclusive rights under U.S. patent and drug laws does not prevent others from pursuing improvements, even in the United States. For example, despite Merck's allegedly preclusive rights (Pet. App. 24a), one of respondent's affiliates, Teva Pharmaceutical Industries, Ltd., has patented an improvement involving "a dosage form suitable for delivering a therapeutic bisphosphonate *such as alendronate*." U.S. Patent No. 6,476,006, abstract (issued Nov. 5, 2002) (emphasis added). Indeed, "blocking" patents—*i.e.*, patents under which each holder may prevent the other from exploiting its own invention in the most effective way—frequently result when a later inventor patents an improvement on an earlier invention. *See Amgen, Inc.* v. *Hoechst Marion Roussel, Inc.*, 339 F. Supp. 2d 202, 287 & r.104 (D. Mass. 2004) (in biotechnology, "blocking patents are common"); *see also Prima Tek II, L.L.C.* v. *A-Roo Co.*, 222 F.3d 1372, 1379 n.2 (Fed. Cir. 2000) (describing an "often occur[ring]" blocking-patent situation); *cf. Cochrane* v. *Deener*, 94 U.S. 780, 787 (1876) ("One invention may include within it many others, and each and all may be valid at the same time."). These realities refute the panel's unsupported assertion that pre-existing rights prevent innovation by others.

That is not surprising. The exclusive rights the Federal Circuit discusses do not preclude experimentation or commercial exploitation by others. Even when a senior party has such rights, other parties may still develop and exploit improvements by, for example, (1) patenting the idea for an improvement, (2) obtaining a license with respect to the pre-existing rights, (3) developing and exploiting an improvement abroad, or (4) pre-commercialization development and testing "reasonably related to the development and submission of information" under certain federal laws, 35 U.S.C. § 271(e)(1); *see also Merck KGaA* v. *Integra Lifesciences I, Ltd.*, 125 S. Ct. 2372, 2380 (2005). The possibility of exploitation abroad is particularly easy to understand and impossible

to deny. PhRMA's members spent an estimated $8.2 billion on foreign research and development in 2004 alone, PhRMA, *Pharmaceutical Industry Profile 2005—From Laboratory to Patient: Pathways to Biopharmaceutical Innovation* 2 fig. 1.1, *available at* http://www.phrma.org/publications/publications//2005-03-17.1143.pdf, and respondent Teva Pharmaceuticals USA is itself a U.S. subsidiary of a foreign corporation.

In addition to being groundless, the Federal Circuit's per se rule is unfair. It discriminates against innovators who bring their inventions to the Patent Office and the market at an early stage—thus disclosing them to the public, as patent law encourages, *see Bonito Boats, Inc.* v. *Thunder Craft Boats, Inc.*, 489 U.S. 141, 150-151 (1989)—and who later improve their original inventions. Under the Federal Circuit's new rule, such innovators will typically find themselves barred from using commercial success either to establish an improvement's patentability before the PTO or to defend an improvement patent in later litigation. This bar on citing commercial success in the securing or defense of improvement rights lessens the value of patent rights all along the chain, by making the original rights a less desirable basis for further innovation and by making the improvement rights both less attainable and, if attained, less secure. The Federal Circuit's rule thus decreases the incentive offered by the patent system both for initial inventions and for improvements by the holder of the original rights.

The situation is different for third-party improvers. They will likely be able to rely on commercial success to confirm the validity of *their* follow-on patents because, even according to the Federal Circuit's logic, there will have been at least one "other"—the holder of the rights to the original invention—who could have developed the improvement but did not. Hence, an improvement patent will be both easier to obtain and more secure against challenge, and thus more valuable, when it is developed by a third-party improver.

That result is inconsistent with the goals of patent law. The law should encourage improvements to existing inven-

tions without regard to who makes them. "A level playing ground for the marketplace of ideas" is the surest means to serve the constitutional purpose of "promot[ing] the Progress of . . . useful Arts," U.S. Const. art. I, § 8, cl. 8. *Panduit Corp.* v. *Denniston Mfg. Co.*, 810 F.2d 1561, 1573-1574 (Fed. Cir. 1987). By reducing the reward offered for improvements by the holder of the original patent—who will often be positioned to develop them most quickly and at lowest cost—the Federal Circuit's rule plays favorites to the detriment of the public.

III. The Decision Below Will Affect A Wide Range Of Cases And Transform Commercial Success Into An Issue Requiring A Complex Threshold Inquiry

The Federal Circuit has already made clear that its new approach to commercial success reaches far beyond this case. In *Syntex (U.S.A.) LLC* v. *Apotex, Inc.*, 407 F.3d 1371, 1379, 1383 (Fed. Cir. 2005), the court vacated a holding of nonobviousness and directed that, on remand, "the district court should consider the impact of the *Merck* analysis." Whenever "the active ingredient in [a patented] formulation was previously patented," the court instructed, "the trial court should carefully consider whether the nexus requirement of our law is satisfied." *Id.* Moreover, because "the *Merck* analysis" makes no distinction on technological grounds, its effects will not be confined to pharmaceutical inventions but will extend to improvement patents in all areas.

Those effects warrant review by this Court. Like technological progress in general, pharmaceutical innovation is frequently cumulative and incremental. Albert Wertheimer et al., *Too Many Drugs? The Clinical and Economic Value of Incremental Innovations*, in 14 *Investing in Health: The Social and Economic Benefits of Health Care Innovation* 77, 78 (I. Farquhar et al. eds., 2001). Of the 996 new drug applications approved by the Food and Drug Administration from 1994 through 2004, 597 were for improvements to, or new uses for or variations of, existing drugs or administra-

tion regimens.[4] The value of such improvements is significant. By reducing side effects (as in this case), improving effectiveness, or enabling a choice among therapies that can be tailored for individual patients, diseases, or symptoms, a diverse array of related drugs and treatment formulations can significantly improve both medical results and patients' quality of life. *Id.* at 78-79.

Despite their importance, such improvements necessarily have strong ties to pre-existing art and are therefore especially vulnerable to allegations of obviousness made in hindsight. Like other "secondary considerations," commercial success is meant to help courts guard against such hindsight bias and "resist the temptation to read into the prior art the teachings of the invention in issue." *Graham*, 383 U.S. at 36. Yet the Federal Circuit has now selectively eliminated that protection for the entity perhaps most likely to pursue an improvement—the original patent holder. That departure from this Court's teaching threatens to slow the rate of innovation in the pharmaceutical industry. *Cf.* Federal Trade Commission, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy*, ch. 3, p. 11 & n.48 (2003) (reporting estimate that, without patent protection, pharmaceutical "innovation would decrease by approximately 60%"), *available at* http://www.ftc.gov/os/2003/10/innovationrpt.pdf; Henry G. Grabowski, *Patents and New Product Development in the Pharmaceutical and Biotechnology Industries*, in *Science and Cents: Exploring the Economics of Biotechnology* 87, 88 (J. Duca & M. Yücel eds. 2003) (discussing "[t]he importance of patents to pharmaceutical innovation"), *available at* http://www.dallasfed.org/research/pubs/science/index.html.

In a wide array of cases, the Federal Circuit's reformulation will also complicate patent litigation—and thereby add to the cost of defending and enforcing patent rights—in a

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[4] Food and Drug Administration, *CDER NDAs Approved in Calendar Years 1990-2004 by Therapeutic Potential and Chemical Type* (Mar. 22, 2005), *available at* http://www.fda.gov/cder/rdmt/pstable.htm.

way that undermines the basic purpose of the commercial success inquiry. *Graham*'s "secondary considerations" of nonobviousness are meant to provide relatively simple, non-technical, objective evidence of nonobviousness, as judged by a marketplace whose opinions are not litigation-driven. They are useful because they "focus attention on economic and motivational rather than technical issues and are, therefore, more susceptible of judicial treatment than are the highly technical facts often present in patent litigation." 383 U.S. at 35-36; *cf. Arkie Lures, Inc.* v. *Gene Larew Tackle, Inc.*, 119 F.3d 953, 957 (Fed. Cir. 1997).

Accordingly, until now the rule was that once a patent holder provided evidence of a "nexus between commercial success and the patented invention," it became the challenger's "burden to show that [such evidence] should not be given weight." *Winner Int'l Royalty Corp.* v. *Wang*, 202 F.3d 1340, 1350-1351 (Fed. Cir. 2000) (internal quotation marks omitted). "A prima facie case of nexus [was] generally made out when the patentee show[ed] both that there [was] commercial success, and that the thing (product or method) that [was] commercially successful [was] the invention disclosed and claimed in the patent." *Demaco Corp.* v. *F. von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 1392 (Fed. Cir. 1988). Requiring further threshold proof that commercial success was "*not* due to factors other than the patented invention" was viewed as "unfairly burdensome, and contrary to the ordinary rules of evidence." *Id.* at 1394 (emphasis in original).

The decision below upsets the established balance of burdens between patent defender and challenger. As part of the threshold inquiry into commercial success, the patent holder will now have to show (1) that commercial success has a further "nexus" with the "failure of others" to invent the improvement, and (2) that the patent holder lacked pre-existing exclusive U.S. rights to the improved invention. In *Syntex*, the Federal Circuit confirmed that these requirements are, like the previous requirement of a causal "nexus," *threshold* burdens that a patent holder must carry to estab-

lish the very relevance of commercial success. 407 F.3d at 1383 ("the trial court should carefully consider whether the *nexus requirement* of our law is satisfied" (emphasis added)). Thus, a patent holder invoking commercial success must now show at the threshold not only that the success was attributable to the invention, but also that there was a competitive market to develop the invention in the first instance.

Proof that such a market existed will often require just the sort of litigation over "technical issues" that reference to "secondary considerations" is meant to avoid. *Graham*, 383 U.S. at 35-36. In almost any situation, there will be both patent and non-patent barriers to market entry that patent challengers will be able to argue break the inferential link between commercial success and the failure of others. Parties can now routinely expect to litigate whether past market conditions permitted competition in innovation. The Federal Circuit has thus added to the already high cost of enforcing patent rights by transforming commercial success into a complex inquiry from the start. Yet "secondary considerations" are intended not to complicate analysis, but to allow straightforward, objective evidence to act as a real-world check on a court's analysis of otherwise technical issues. *Id.*; *see also Reiner*, 285 F.2d at 504, *cited in Graham*, 383 U.S. at 36; Robbins, *supra*, at 1171-1172.

For these reasons, the decision below transforms the commercial success inquiry in ways that are inconsistent not only with its logic, but with its basic purposes as identified by this Court. This transformation will affect not only cases involving pharmaceuticals, but improvement cases in all fields of invention. The decision accordingly warrants this Court's review.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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MERCK & CO., INC.,

Petitioner,

v.

TEVA PHARMACEUTICALS USA, INC.

Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

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REPLY BRIEF FOR PETITIONER

Teva's brief in opposition defends very little of what a divided panel actually said in reversing the district court and invalidating one of the most important patents in the pharmaceutical field. Rather, Teva's brief advances numerous factual contentions that the finder of fact did *not* accept, and legal contentions that are *not* the ones the Federal Circuit gave as its bases for reversing. Such a document – akin to first-instance proposed findings of fact and conclusions of law in a trial court – only underscores that the gravamen of Teva's case is issues it lost in the *trial* court, and that no sustainable basis for reversal on appeal existed. To reverse nevertheless, the Federal Circuit acted as if it were the original factfinder and adopted a new rule of law on commercial success, producing several dissents.

Teva does not dispute the continuing disagreement within the Federal Circuit, refute the disarray caused by that court's *de novo* approach to reviewing district court claim construction decisions, or even defend that approach. The Federal Circuit's insupportable methodology has become entrenched by three successive en banc cases[1] declaring and reaffirming that claim construction involves no underlying factual issues to which the "clearly erroneous" standard of Rule 52(a) attaches – a fundamentally mistaken position that warrants review by this Court.

Similarly, Teva does not defend the Federal Circuit's trampling of Rule 52(a) en route to declaring Merck's '329 patent invalid for obviousness under 35 U.S.C. § 103(a). Instead, Teva falsely presumes that the "same invention" was in the prior art – when in fact the prior art contained *no invention at all*. Thus, Teva avoids confronting the Federal Circuit's disregard of the district court's factual determinations concerning this Court's "*Graham* factors" and the secondary considerations required in

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[1] See *Phillips* v. *AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc); *Cybor Corp.* v. *FAS Techs., Inc.*, 138 F.3d 1448 (Fed. Cir. 1998) (en banc); *Markman* v. *Westview Instruments, Inc.*, 52 F.3d 897 (Fed. Cir. 1995) (en banc), aff'd in part, 517 U.S. 370 (1996).

evaluating obviousness. Indeed, Teva recasts the Federal Circuit's invalidity rationale as rejecting a "legal" theory (Opp. 15) rather than defending its impermissible reweighing of the district court's detailed findings, even though the Federal Circuit summarily declared blanket "clear error" in every finding contrary to its desired invalidity outcome. Pet. App. 22a; see also Pet. App. 16a ("As explained below, we find clear error in the trial court's findings on these underlying facts.").

Finally, in defending the Federal Circuit's declaration that Merck's strong evidence of "commercial success" and "nexus" to the claimed invention was entitled to "no force," Teva ignores that the Federal Circuit again impermissibly reweighed this evidence *and* announced a new rule of law making a long-standing category of evidence irrelevant.

I. No Issue in this Case Is "Moot"

Teva tries to sidestep Merck's first question by alleging that the parties' vigorous dispute about claim construction is "moot." Opp. 8. Teva points to nothing outside of this litigation that has created any arguable source for the alleged mootness. Instead, Teva's "mootness" theory arises solely from the footnote in which the Federal Circuit's majority declared that "[i]t makes no difference to this conclusion [of invalidity] whether the court begins with the claim construction set forth by the panel or by the dissent." App. 16a n.10. Based on nothing more, Teva argues that correcting the Federal Circuit's flawed *de novo* methodology and erroneous construction in this case would not affect the outcome. Opp. 9. That is simply wrong.

As explained at Pet. 23 n.14, the Federal Circuit's footnoted attempt to insulate its claim construction approach and result from further scrutiny is belied by its own detailed claim construction analysis and its concession that its invalidity holding was reached "[i]n light of the corrected claim construction." Pet. App. 15a. At no prior point did Teva accept Merck's vastly different claim construction or contend that the parties' lengthy and hotly contested claim construction dispute was irrelevant. Even now, Teva tries to bolster the Federal Circuit's acceptance

of the claim construction rejected by District Judge Farnan. Opp. 9-13.

In this case, as in any other patent case, a complete and proper claim construction is a necessary prerequisite to and thus inextricably intertwined with any subsequent invalidity analysis. An exception to that rule cannot be created by a Federal Circuit footnote that really does nothing more than expose that court's result-oriented invalidity approach. In *Cardinal Chem. Co.* v. *Morton Int'l*, 508 U.S. 83 (1993), this Court halted the Federal Circuit's practice of vacating district courts' invalidity holdings (in cases with declaratory judgment counterclaims) on the ground that all invalidity issues were rendered "moot" once the Federal Circuit affirmed a finding of no infringement. Similarly, a declaration of the type in the Federal Circuit's footnote cannot moot this Court's ability to review the Federal Circuit's *de novo* claim construction.

Notwithstanding footnote 10, the Federal Circuit majority proved that it thought the parties' dispute about claim construction *did* matter to the outcome by resolving that dispute in a lengthy discussion, which the court presumably did not intend to constitute a mere advisory opinion. The court even described its reversal on obviousness as being reached "[i]n light of the corrected claim construction." Pet. App. 15a. Judge Rader's panel dissent focused *entirely* on claim construction, reflecting his view that claim construction had "consequences" (Pet. App. 26a) in this "very close case" (*id.* at 33a) in which the district court's "diligent and intelligent process *and resolution* earned more respect than it received" (*id.* (emphasis added)).[2]

Teva asserts that "the difference between exactly 70 mg * * * and 80 mg, specified by the *Lunar News*, is not a distinc-

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[2] It is fanciful to suggest (Opp. 7) that Judge Rader did not urge a different outcome for this case. Judge Rader's repeated references to the closeness of this case, his express citation of the district court's *resolution* of the case, and the very labeling of his opinion as a dissent rather than a concurrence in the judgment all confirm that he would have affirmed rather than reversed the district court.

tion that could make Merck's invention unobvious." Opp. 9. It is, however, no mere coincidence that the district court rejected both Teva's claim construction and its obviousness defense, whereas the Federal Circuit accepted both. The district court correctly understood that such a dosing difference can be significant within the art, and found that Teva's evidence at trial failed to prove the equivalence of the two doses. "[A]lthough Dr. Russell testified that 80 mg and 70 mg are the same for all practical purposes, * * * in rendering his opinion Dr. Russell did not take into account this Court's construction * * *. Dr. Russell provided no evidence to support his conclusion that 70 and 80 mg were equivalent." Pet. App. 72a. Not only were the validity findings tied to the claim construction, but the *finder of fact* was not persuaded that the difference between 80- and 70-mg doses is insignificant based on the evidence at trial. Teva and the Federal Circuit have no legal basis for insisting on such a finding.

II. This Court Should Review and Reject the Federal Circuit's Refusal to Give Deferential Review to Factual Findings Underlying Claim Construction

Other than its incorrect "mootness" contention, Teva offers nothing to rebut Merck's showing why resolution by this Court of the correct manner of appellate review applicable to district court claim constructions rulings is critically important. Indeed, Teva's conspicuous refusal to cite, much less defend, the Federal Circuit's en banc decisions in *Markman*, *Cybor*, and *Phillips* confirms the need for this Court to review and correct that clearly flawed appellate methodology. See Pet. 18-19 & n.8.

Teva's efforts to defend the merits of the Federal Circuit's *de novo* claim construction are misplaced and mistaken. First, as Judge Rader pointed out, "[t]his is the classic 'close case,' so close in fact that ultimately two federal judges (one of whom conducted an entire bench trial on this issue) and the United States Patent and Trademark Office agreed with [Merck] and two federal judges agreed with [Teva]." Pet. App. 32a. This is exactly the kind of case where there could be no clear error in

the underlying findings. *Anderson* v. *City of Bessemer City*, 470 U.S. 564, 574 (1985). Hence, if this Court decides that claim construction does involve resolving underlying issues of fact, it would be immaterial whether this Court or the Federal Circuit agrees with Merck or with Teva. *Id.* at 573-574. Resolution of the question posed would be determinative of the disputed claim phrase here – the district court's admittedly reasonable construction would have to be accepted, even if an appellate court conceived a construction it thought "more reasonable." Pet. App. 13a.

As the district court understood, the '329 patent contains an explicit definition for the entire claim phrase that was truly at issue. Claim 23, the only claim addressed in Teva's opposition, recites "[a] method for treating osteoporosis * * * comprising administering *about 70 mg of alendronate monosodium trihydrate, on an alendronic acid basis*." Pet. 3. The definition explicitly states that "the phrase 'about 70 mg of a bone resorption inhibiting bisphosphonate selected from the group consisting of alendronate, pharmaceutically acceptable salts thereof, and mixtures thereof, on an alendronate acid active weight basis' *means* that the amount of the bisphosphonate compound selected is calculated based on 70 mg of alendronic acid." Pet. 7 (quoting C.A. App. 3594-95) (emphasis altered). Thus, the specification defines the entire phrase within quotes, not just for the word "about" and not just for the phrase "about 70 mg" that appear within the overall defined phrase.

Neither Teva nor the Federal Circuit has made any attempt to be faithful to what the patent says the disputed phrase "means." The Federal Circuit resorted to declaring its "belie[f]" that the patent's definitional clarity was "likely an inadvertent error," Pet. App. 13a n.8, an exercise of appellate factfinding so bizarre that Teva says not one word in defense of it. Yet Teva resorts to what may be an even more bizarre tactic, simply omitting the word "means" from its quotation of the patent's definition – despite emphasizing that the key question is whether the specification says in so many words what the key phrase "*means*." See Opp. 10. Such gymnastics to avoid the patent's

clear definition both show the error of the decision below and confirm that the standard of review mattered greatly in this case.

In any event, resolution of any ambiguity in the claim language requires a trial court to evaluate the conflicting evidence cited by both parties bearing on the ambiguous word or phrase. Merck's citation to certain portions of the specification and Teva's citation to others does not change the fundamental nature of the pertinent inquiry – a resolution of conflicting evidence, which is factfinding, even when done by a trial court on a matter reserved for its (rather than a jury's) decision. Thus, as amicus BPLA observes, "this case * * * provides an excellent opportunity to reconsider the Federal Circuit's *de novo* review standard." BPLA Amicus Br. 4.

Second, Teva's defense of the Federal Circuit's claim construction misdirects this Court by addressing a claim phrase that was never at issue. Contrary to Teva's position, no one at trial disputed the ordinary meaning of the term "about" and no court should have decided whether Merck's specification clearly redefined the claim phrase "about 70 mg" to mean "exactly 70 mg." Opp. 9. Even if the meaning of the term "about" or "about 70 mg" were both at issue and ambiguous, resolving their meaning would similarly be a question of fact to be determined by weighing the conflicting evidence related to those terms.[3]

Finally, Teva complains that Merck would require the Federal Circuit always to defer to a district court's construction even if it was contrary to the entire patent. Opp. 12. That is untrue. First, if all the evidence supports only one reasonable interpretation, there is no ambiguity, and no factfinder should find otherwise. In that case, a district court's contrary construction

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[3] Where expert or inventor testimony is offered, credibility determinations may also factor into a trial court's fact finding. See Pet. 8. No Merck witness testified on the meaning of "about 70 mg" because that phrase was not at issue. Opp. 12. While Teva concedes that the district court did not credit Teva's expert on that phrase, Teva ignores that the district court recognized that Dr. Russell understood the specification's express definition for the entire claim phrase at issue. Pet. 8.

can and should be reversed, as would any other factfinding on which the evidence permits no reasonable dispute. See *Warner Jenkinson Co.* v. *Hilton Davis Chem. Co.*, 517 U.S. 17, 39 n.8 (1997). Here, however, Teva merely recites its version of the disputed evidence in disregard of Merck's directly contrary evidence credited by the finder of fact (Pet. App. 58a-64a). This highlights rather than disproves the existence of underlying factual disputes that were plausibly resolved at trial.

Teva's opposition also confirms that the Federal Circuit's form of *de novo* review wrongly encourages patent litigants to proceed on appeal as if they have free license to reargue the factual issues underlying their claim construction positions from scratch. This Court should not allow the Federal Circuit to ignore Rule 52(a) any longer. Moreover, there can be no question that the Federal Circuit's *de novo* methodology that refuses to accord Rule 52(a) deference to district court fact findings has spawned widespread and unacceptable confusion, unpredictability, and uncertainty in patent cases for more than a decade. See Pet. 18-19; BPLA Amicus Br. 9-11. The time has come for this Court to review that entrenched but controversial Federal Circuit practice, and this "classic 'close case'" (Pet. App. 32a) is the perfect vehicle in which to do so.

III. This Court Should Correct the Federal Circuit's Insistence that Any Factual Finding that Got in the Way of the Majority's Obviousness Conclusion Was Automatically "Clearly Erroneous"

With obviousness, as with claim construction, Teva refuses to address or refute the substance of Merck's challenge to the Federal Circuit's increasingly bold disregard of the limits on its appellate review authority under Fed. R. Civ. P. 52(a). Contrary to Teva's assertion (Opp. 13), Merck is not seeking to alter an appellate court's role as specified by this Court in *Bessemer City*, but is urging this Court to rein the Federal Circuit back into operating within those important limits. Hence, Teva has left wholly unrebutted Merck's showing that the Federal Circuit's approach to *de novo* review of claim construction has equally infected its approach when reviewing other legal issues

such as obviousness that indisputably have underlying factfindings. See Pet. 23-24.

Teva's opposition argues invalidity on the ground – *not* accepted by the Federal Circuit – that the "same invention" was allegedly in the prior art, rather than confronting the district court's explicit and detailed findings (Pet. App. 83a-94a) showing why the differences between Merck's invention and the prior art as a whole were nonobvious. Even the Federal Circuit agreed that the *Lunar News* articles did not disclose the "same invention" as the '329 patent and thus could not anticipate under 35 U.S.C. § 102. Pet. App. 16a. Indeed, the *Lunar News* articles on which Teva and the Federal Circuit exclusively rely do not disclose an invention, but merely contain an untested suggestion and a hope for future improvements.

The two *Lunar News* articles merely state that alendronate "*potentially could be* given in a 40 or 80 mg dose once/week" or that "[a]n intermittent treatment program (for example, once per week * * *) * * * *needs to be tested*." C.A. App. 3677, 3641 (emphasis added). Teva's Wright Brothers analogy (Opp. 16 n.4) usefully illustrates the point: Teva's premise that the *Lunar News* suggestions constitute an earlier invention of the '329 patent would mean that the Wright Brothers' patents would have been invalidated by countless articles in the pre-1900s predicting that man one day potentially could build bird-like flying machines and suggesting that such ideas need to be tested.

The critical question for this Court's review is whether to condone the Federal Circuit's cavalier practice of reaching its own legal conclusion before announcing its disregard or reversal of any contrary district court finding. The issue is not whether this Court would agree in the first instance with Merck and the district court or with Teva and the Federal Circuit on whether Merck's invention was obvious. Rather than trying to defend the Federal Circuit's inverted approach, Teva advances the preposterous propositions that the Federal Circuit merely rejected "Merck's legal theory" (Opp. 15) and "did not base its decision on a rejection of district court fact findings." Opp. 16. It is telling that Teva mischaracterizes the Federal Circuit's stated

basis for its obviousness conclusion rather than attempting to justify the court's *de novo* review methodology.

Contrary to Teva's premise, Merck's nonobviousness proof did not require "nullifying" the Lunar News articles as prior art, nor did Merck's position require the district court to find that Dr. Mazess was not an expert. Opp. 6, 15-16. Instead, Merck rebutted Teva's evidence with extensive evidence showing that Dr. Mazess's untested conjecture would not have persuaded those skilled in the art of treating osteoporosis patients at the pertinent time that alendronate could be safely administered at doses higher than 20 mg. See Pet. 9-10. Regardless of his credentials, the district court properly weighed all the conflicting evidence, including the other prior art and expert testimony, and found that Dr. Mazess's naked suggestions provided no advance to the art and could not overcome the prior art teachings as a whole. See Pet. 25-27. Thus, it is the Federal Circuit's *sua sponte* findings on appeal that are unsupported. Its invalidity conclusion is the product of improper reweighing of disputed evidence and result-oriented hindsight, a continuing problem in that court worthy of this Court's review.

IV. As the Amicus Briefs Attest, the Federal Circuit's Refusal to Give Weight to the Commercial Success of an Improvement Patent Merits Review

Merck offers two main points regarding Teva's lengthy but mostly irrelevant defense of the Federal Circuit's misguided new rule disabling the probative value of commercial success evidence in cases where a patentee improves its own patented invention. Pet. App. 23a-24a. First, the most Teva can assert now is that the commercial success of Merck's once-weekly Fosamax® product "is not necessarily attributable to its non-obviousness." Opp. 18. On its face, a proposition that is "not necessarily" true is the epitome of a disputed factual question, which the district court resolved in favor of Merck. Pet. App. 91a-93a. The Federal Circuit's and Teva's preference that the district court have given Merck's evidence less weight is not a proper basis for inventing on appeal a new rule of law that throws that evidence out altogether.